UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	

REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR RECONSIDERATION OF THE COURT'S DECEMBER 13, 2017 ORDER ON GENERAL CAUSATION

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INTRODUCTION

For all their many pages of argument and reams of exhibits, Plaintiffs never dispute any of the following points:

- Plaintiffs cannot identify any test that has shown that the Bair Hugger blanket emits bacteria.
- Plaintiffs' medical experts all rely on the operating room "forcefield" concept as the foundation for their theory that the Bair Hugger system disrupts that "forcefield" and causes bacteria-laden particles to enter the surgical wound.
- Said Elghobashi, Plaintiffs' airflow expert, testified that the "forcefield" concept was "silly" and "rubbish," and that anyone who uses the concept "does not know turbulence."
- Elghobashi testified that his CFD does not account for sources of air currents and heat that would be found in any OR, including movement of surgical personnel, doors opening and closing, and surgical equipment.
- Plaintiffs have no study that accounts for other sources of air currents that would be found in the OR, and concede that even a well-designed study cannot account for such variables. Opp. 25.

- Despite the heavy reliance of Plaintiffs' experts on Elghobashi's CFD, it never shows a particle entering the surgical wound.
- Plaintiffs' other studies, they concede, "were not designed to investigate whether particles infected the patient." Opp. 24.
- The Jeans study found a statistically significant reduction in post-surgical infections when MSSA screening was introduced. In the Observational Study, few Bair Hugger patients were screened for MSSA, while all the HotDog patients were screened.
- Plaintiffs concede the Observational Study "cannot 'prove' causation." Opp. 34.

The question before the Court is the admissibility of the opinions of Plaintiffs' *experts* about the scientific evidence, not the admissibility of Plaintiffs' *lawyers'* arguments about that evidence. Plaintiffs offer no testimony from Elghobashi approving Plaintiffs' attempt to recharacterize his trial testimony as "quibbles over semantics." Plaintiffs offer no response from their medical experts about Elghobashi's repudiation of the protective "forcefield," the key concept underlying their opinions and Plaintiffs' theory of causation. Plaintiffs offer no response from Dr. Samet, Plaintiffs' epidemiology expert, to Dr. Borak's opinion on the significance of the Jeans study, which shows MSSA screening was a likely confounder in the Observational Study. Indeed, Plaintiffs' experts offer no basis for this Court to conclude that they have reliably addressed Elghobashi's testimony and the new scientific evidence, or that they should be allowed to testify at future trials.

Nor is there any explanation from Plaintiffs' medical experts about why they ally themselves with the 2% of the medical community who reject the 2018 ICM's conclusion that there is no "strong evidence linking FAW to increased risk of SSI," rather than the 93% who support that conclusion. The 2018 ICM, like the FDA's "Dear Health Care Provider" letter in 2017, reflects the overwhelming – and deepening – consensus within the scientific community that Plaintiffs' allegations lack a basis in sound science. These statements also reflect the pressing need felt by regulators and experts in orthopedics to set the scientific record straight, because some healthcare providers fear being sued or attacked by Scott Augustine or the Plaintiffs' lawyers if they use this life-protecting technology.

For these reasons, as well as the reasons discussed in Defendants' Memorandum, the Court should exclude the opinions of Plaintiffs' medical experts, exclude the model of Plaintiffs' computational fluid dynamics (CFD) expert, and grant summary judgment in favor of Defendants.

ARGUMENT

I. BY THE COURT'S ORDER IN *GAREIS*, PLAINTIFFS HAVE BEEN LIMITED TO THEIR AIRFLOW DISRUPTION THEORY.

In *Gareis*, the Court barred Plaintiffs from pursuing their second theory of causation: that the Bair Hugger blanket emits bacteria. The Court concluded that Plaintiffs had failed to offer sufficient proof to support that theory at trial: "[N]o expert brought to the Court's attention has tested the air coming out of a Bair Hugger's blanket and discovered escaping colony-forming units. The test would be feasible; it is certainly not cutting edge." *Gareis*, Dkt. 306, Order 3. Plaintiffs' experts "have examined Bair Huggers

in operation. They have not, however, shown any pathogen coming out of the 'business end' of the Bair Hugger, the perforated blanket." *Id.* In their Opposition, Plaintiffs contend that the Court's analysis was specific to *Gareis*, and that the Court meant only that Plaintiffs' theory failed because they had not tested the Bair Hugger blanket while it was being used in Mr. Gareis's hip surgery. Opp. 6-7.

However, like their failure of proof in *Gareis*, to this day Plaintiffs have not come forward with *any* test of a Bair Hugger blanket that shows colony-forming units escaping. Plaintiffs protest that "even if case-specific reports in *Gareis* did not show 'any pathogen coming out of the 'business end' of the Bair Hugger,' **it still emits bacteria**." Opp. 7 (bold in original). But Plaintiffs still fail to cite any scientific support for that claim, just as they failed to do so in *Gareis*. There is no new report from Jarvis or anyone else conducting this testing. Indeed, their sole support for this statement is Defendants' purported admission that they had not "conducted any internal testing" to refute Plaintiffs' theory.

Defendants do not bear the burden of proof here. Plaintiffs do, and they cannot meet it. Nor can Plaintiffs' theory go forward based on Plaintiffs' vague and improbable promise that they may perform such a test "in future cases." Opp. 7. The law does not permit Plaintiffs to wait to do such testing; they have the burden of proof *now* and they have not met it. *See, e.g.*, *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 450 (S.D.N.Y. 2017) ("[I]t is not that experts are insincere in their opinions or that their opinions may not some day be validated through scientific research and experiment; it is simply that the law cannot wait for such a confirmation." (quotation omitted)).

For these reasons, and consistent with the Court's *Gareis* decision, Plaintiffs are now confined to their airflow disruption theory.

II. ELGHOBASHI'S TRIAL TESTIMONY VITIATED PLAINTIFFS' AIRFLOW DISRUPTION THEORY OF CAUSATION.

A. According to Plaintiffs' Medical Experts, the Bair Hugger System Introduces Turbulent Airflow into the "Forcefield" Around the Patient.

At the *Gareis* trial and in their reports, Plaintiffs and their medical experts argued that steady "unidirectional" flow of filtered air from the HVAC system creates a protective "forcefield" around the patient on the operating table. They argued that the warm air introduced by the Bair Hugger system creates turbulence and disrupts that "forcefield." The introduction of turbulence, they claim, allows particles to be swept by air currents toward the patient and into the wound. DX13, Trial Tr. 366:2-367:1 (Stonnington), 512:12-513:4 (Jarvis); PX2, Samet Rpt. 13. Plaintiffs need this "forcefield" argument because otherwise it is impossible to isolate the Bair Hugger system as the only thing in the operating room that disrupts airflow.[1] But as set forth in Defendants' Memorandum, at the *Gareis* trial Elghobashi rejected the forcefield concept as "absolute nonsense" and

[1] None of Plaintiffs' experts offers any methodology for ruling out other sources of airflow disruption (*e.g.*, door openings, movement of medical personnel, etc.) in specific cases. *See Johnson v. Mead Johnson, LLC*, 754 F.3d 557, n.2 (8th Cir. 2014) ("[T]he experts 'rule in' the reasonable plausible causes of injury and then 'rule out' or eliminate them from least to more plausible until a most plausible cause emerges."). Moreover, arguing that the Bair Hugger system adds to other turbulence cannot fulfill Plaintiffs' burden to demonstrate that their injuries would not have occurred without the use of the Bair Hugger system (either as a "but for" cause or "substantial contributing factor"). *See, e.g., Ford Mot. Co. v. Ledesma*, 242 S.W.3d 32, 46 (Tex. 2007) (causation requires proof that the product was a "substantial cause of the event in issue . . . without which the event would not have occurred").

"rubbish." Trial Tr. 973:9-19, 974:4-14, 978:15-19. Elghobashi thereby gutted the foundational premise of Plaintiffs' medical experts' general causation opinions.

None of Plaintiffs' medical experts has responded to Elghobashi's testimony. Dr. Samet, who opined that the Bair Hugger system disrupts the "protective unidirectional flow" of the OR HVAC system, has not submitted a response. Nor has Dr. Stonnington, who testified to the jury about the "forcefield" before Elghobashi took the stand. Even Dr. Jarvis, who has authored two reports in bellwether cases since the *Gareis* trial, continues to act as if Elghobashi's testimony never happened, repeatedly invoking Elghobashi's name in support of the idea that the Bair Hugger system disrupts the "sterile field."[2] PX54, Jarvis *Trombley* Rpt. 8 ("According to Dr. Elghobashi's study, the Bair Hugger causes significant disruption of OR airflow, leading to increased number of particles and skin squames over and in the sterile field."). One suspects Elghobashi will not testify at any future bellwether trial, and instead Plaintiffs will offer Jarvis to "interpret" Elghobashi's CFD to the jury.

Rather than having their experts address Elghobashi's testimony, Plaintiffs attempt to downplay it, characterizing the whole issue as a "quibble over semantics." Opp. 10. They assert that "[b]oth Plaintiffs' and 3M's experts recognize that the goal of operating room airflow – whether called 'laminar,' 'unidirectional,' or 'turbulent,' – is to protect patients by sweeping airborne particles below and away from the sterile field." *Id.* at 9. Defendants

[2] In both reports, Jarvis claims Elghobashi's CFD "confirm[s]" the Bair Hugger system is the most likely cause of the plaintiff's PJI. PX54, Jarvis *Trombley* Rpt. 11; DX17, Jarvis *Axline* Rpt. 12.

agree that is the *goal*. Elghobashi's position is that the goal is not achieved – and cannot be achieved – by operating room HVAC systems. Anyone who says otherwise, according to Elghobashi, "does not know turbulence." Trial Tr. 974:4-14.

Plaintiffs further assert that Elghobashi had no problem with the concept of a forcefield; rather, he just did not like the term. They cite no testimony from Elghobashi to support this gloss, and there is none. Plaintiffs also point out that Elghobashi's CFD shows air being directed down and away from the surgical table when the Bair Hugger system was turned off. Opp. 11. That proves nothing, because the CFD admittedly does not show a realistic OR. As Elghobashi explained, his CFD does not reflect many sources of turbulence and particles that one would expect in a real operating room. Trial Tr. 976:12-16, 952:3-4. Opening and closing of doors – which does not occur in his CFD – would increase turbulence. *Id.* at 961:25-962:1 ("If you open the door or let the people move, you will enhance the spreading of squames.").

Elghobashi also agreed that in a real OR the medical personnel move, unlike the stationary figures in his CFD. *Id.* at 961:7-9. In his report, Elghobashi further noted that "other medical equipment within the operating room (surgical lights, tables, patient, computers, etc.), motion of surgeon's arms and their bending motion can disrupt this air flow and create wakes, flow unsteadiness, and turbulence, thereby increasing the amount of cfu in the OR." DX3, Elghobashi Rpt. 1-2 (internal citation omitted); *see also* Def. Mem. 14-15 (explaining why other sources of air currents are important to causation).

Plaintiffs' response, boiled down, is that that Defendants' CFD expert also did not account for these factors. Opp. 15-17. But Elghobashi, in the testimony cited above, agreed

that these sources matter. These other sources of heat and currents help him explain why there is no such thing as a "forcefield" in a real OR. Moreover, the fact that Dr. Abraham's CFD does not account for certain sources of air currents in real ORs does not make Elghobashi's CFD any more realistic. For example, Abraham testified in *Gareis* about the importance of considering door openings on OR airflow. Discussing the video from a study on the impact of door opening, Abraham testified:

> I mean what that video clearly showed is that when someone opens the door and walks into a room, they create tremendous air movement and disturbances, and those disturbances extended, I think we saw, about 90 percent of the way across the room. Insofar as neither CFD calculations in this case had opening doors, I mean, we [Elghobashi and Abraham] both ignored opening doors, and they are major. They have a major effect, and so I do think this is relevant to the current case.

DX18, Trial Tr. 1865:3-15. Plaintiffs offer only argument, not science, for their contention that opening doors has no meaningful impact on operating room airflow.

At bottom, Plaintiffs' theory – that the Bair Hugger causes PJIs because it alone disrupts the "forcefield" in real surgeries in real ORs – is vitiated by Elghobashi's testimony. Plaintiffs' medical experts lack a reliable basis to extrapolate from Elghobashi's oversimplified, cartoonish OR, to what occurs in a real OR. *See*, *e.g.*, *Mirena IUD*, 169 F. Supp. 3d at 441-42 (excluding general causation expert's opinion, which was based on a lab test that did not replicate real anatomy). Accordingly, their airflow disruption theory should be excluded. *See Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags behind science; it does not lead it.").

B. The CFD Never Shows Squames Entering the Surgical Wound.

Plaintiffs do not dispute that Elghobashi's CFD never shows squames entering the surgical wound. They highlight Elghobashi's expertise and the "400 hours of super-computer processing time" used to create the animation (Opp. 5), but all that expertise and effort still could not deliver one squame to the wound. Plaintiffs ask the Court to speculate that, if the animation were to run longer, it would show particles landing in "the vicinity of" the surgical wound. Opp. 22. But they offer no testimony from Elghobashi or any other authority to support that speculation, much less that the squames would enter into the wound itself. Plaintiffs further concede that the other studies upon which they rely "were not designed to investigate whether particles infected the patient." Opp. 24.

Defendants' experts Michael Keen and John Abraham offered a reason why the squames do not enter the surgical wound: the wound creates its own heat plume that provides a natural protective barrier. Def. Mem. 18-19. The wound plume was proposed by the National Institutes of Health, which prepared its own CFD and concluded: "there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection."[3] DX4. Plaintiffs criticize the theory, but it is merely lawyer argument. Neither Elghobashi nor any other of Plaintiffs' experts has opined or testified that there is no wound plume or that it does not provide a protective barrier.

[3] Plaintiffs also assert that the NIH "found that 2% to 5% of particles reached the surgical site." Opp. 23. That is not accurate. NIH reported: "The percentage of squames deposited on the patient was zero when the forced air warmer was on or off." DX4.

For this additional reason, Plaintiffs' experts cannot rely on Elghobashi's CFD to support their causation theory.

C. The Other Studies Relied on by Plaintiffs' Experts Reach No Conclusions about the Bair Hugger's Effect in a Real-World Operation.

Plaintiffs attempt to defend the airflow studies by McGovern, Legg, et al., but Plaintiffs concede those studies do not replicate real-world ORs. Opp. 25. Plaintiffs' also do not dispute that those studies, by themselves, cannot support their airflow disruption theory and inference of general causation. As Plaintiffs insist, their experts did not base their opinions on a single study or a monolithic line of evidence, but on "**all of these sources combined**." Opp. 27 (bold in original). Yet Plaintiffs cite no study that accounts for other sources of air currents and heat in the OR, and they concede that even a well-designed study cannot account for such variables. Opp. 25.

By the same token, none of Plaintiffs' experts explains what happens if one of those sources turns out to be unreliable. If the Court were to conclude, based on Elghobashi's testimony, that the CFD is not a reliable basis for their airflow disruption theory, could they still advance that theory? No, according to Plaintiffs' experts. Jarvis advances the airflow disruption theory "based on the report of Dr. Said Elghobashi's detailed and impressive [CFD] simulation analysis, *together with* the published peer-reviewed literature." PX1, Jarvis Rpt. 24-25 (emphasis added). Samet concludes only that the "full body of evidence," which includes Elghobashi's CFD, "is sufficient to conclude that the Bair Hugger device causally increases risk for deep joint infection." PX2, Samet Rpt. 16. It is Plaintiffs' burden to establish admissibility of their experts' opinions, and they will have failed to carry that

burden if the Court concludes that Elghobashi's CFD does not support their airflow disruption theory.

III. AS CONFIRMED BY THE JEANS STUDY, THE OBSERVATIONAL STUDY CANNOT INDEPENDENTLY SUPPORT AN INFERENCE OF GENERAL CAUSATION.

There can be no serious dispute that Plaintiffs' medical experts also need the Observational Study to reach their opinions. The *Reference Manual on Scientific Evidence* rejects any attempt to infer causation by application of the Bradford-Hill criteria in the absence of epidemiological studies finding an association. *Id.* 599 n.141 (3d ed. 2011).

Jeans underscores and highlights the fundamental defects that Defendants have previously identified in the Observational Study, many of which the Study's authors concede. *See In re Viagra*, 658 F. Supp. 2d 936, 944-45, 950 (D. Minn. 2009) (excluding plaintiff's medical expert based on additional evidence undermining epidemiological study on which the expert relied). Jeans also directly addresses the challenge posed by Plaintiffs' counsel at the *Daubert* hearing that the Observational Study authors had not looked at whether MSSA might be a confounder. DX15, Hrg. Tr. 242:15-18. Moreover, even if the Court disregards Jeans (which it should not do), the fact remains that the Observational Study is too flawed to support general causation on its own.

A. Plaintiffs' Attacks on Jeans Apply Equally to the Observational Study.

Jarvis submitted an expert report in *Trombley*. That opinion forms the primary basis for Plaintiffs' attack on the Jeans study. Jarvis's report identifies "important issues" with the paper. These "important issues" include that it is "not a randomized controlled trial" and the researchers' concession that "improvement in infection rates could have been [due]

to other factors than MSSA screening." PX54, Jarvis *Trombley* Rpt. 15-16. The Observational Study was not a randomized controlled trial, and the authors expressly acknowledged that the association they found could be the product of confounders. As Dr. Reed and colleagues remarked in a paper published in November 2018, the Observational Study "suggested that the risk of developing deep infection up to 60 days after surgery was substantially greater for patients treated with FAW [forced air warming] than RFW [reflective warming], but there were significant confounding factors in this study." DX16, Kumin 6.[4] If potential confounders are reason to disregard Jeans, then the Observational Study should be disregarded as well.

Plaintiffs also argue that Jeans should be disregarded because it is merely an observational study, only found an association between MSSA screen and reduction of SSI rates, and therefore "does not prove causation." Opp. 33-34. If no causation inference can be drawn from an observational study that finds only association, then the McGovern Observational Study likewise provides no reliable foundation for Plaintiffs' experts' general causation opinions.

[4] Plaintiffs assert that another recent paper by Dr. Reed calls for health providers to abandon forced air warming. No such recommendation can be found in the paper. PX53. The point of the paper is that, rather than creating a protective forcefield around the surgical site, "laminar" HVAC systems may do no good or even *increase* the risk of infection. *Id.* at 4. This is another blow to Plaintiffs' "forcefield" theory. The paper also discusses the many sources of wound contamination present during surgery. The paper briefly discusses teh Observational Study, noting "[i]t was proposed that this [forced air warming] may be an explanatory factor in the changed fortunes of LAF [laminar flow] when this warming method was introduced." *Id.* at 7. That is a far cry from saying that the Observational Study was not confounded or that it proves the Bair Hugger system causes PJIs.

Plaintiffs' criticism also falls flat because the Jeans authors undertook a serious effort to address confounders. Unlike the Observational Study, Jeans employed a multivariate analysis and still found a statistically significant difference in infection rates when MSSA screening was introduced. DX11, Borak *Axline* Rpt. ¶ 21b.

Notably, while we have now heard from Jarvis on Jeans, we have heard nothing from Samet and Stonnington. Both relied heavily on the Observational Study in forming their general causation opinions, yet Plaintiffs have not served supplemental statements from either. We do not know what they think, and whether Jeans changes their opinions in any way. Nor do we know whether Elghobashi's trial testimony, where he rejected Plaintiffs' "forcefield" theory, changes their opinions. (Stonnington testified before Elghobashi in *Gareis*.)

The Court should not assume, based on their silence, that they agree with Plaintiffs' arguments. The Court should, at a minimum, exclude their general causation testimony because it does not address this important new evidence. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 426 (S.D.N.Y. 2005) (excluding experts who ignored studies contrary to their opinions and "discussed only the evidence they believed would advance the plaintiffs' position").

B. The Court Did Not Conclude (and Defendants Did Not Concede) that Elghobashi's CFD Is Sufficient to Support General Causation.

Finally, Plaintiffs argue that notwithstanding their experts' own testimony, the Observational Study is not essential to their experts' opinions and that Elghobashi's CFD provides a sufficient foundation by itself. They quote this Court as stating that "Elghobashi's testimony is **sufficient** to support Samet's causal inference." Opp. 28 (bold in original). That is not exactly what the Court said, and the language omitted by Plaintiffs makes a big difference. The Court said that "*Defendants apparently concede that*, once admitted, Elghobashi's testimony is sufficient to support Samet's causal inference." Order 9 (citing page 24 of Defendants' Medical Experts Memorandum). In fact, Defendants did not make this concession, and addressed this statement in a letter sent to the Court shortly after the Order was entered. Dkt. 1029.

On page 24 of their Medical Experts Memorandum, Defendants noted merely that Plaintiffs' medical experts rely on Elghobashi's CFD computer model for a "causal mechanism" for surgical site infections. Dkt. 750. This is not the same as saying that the CFD provided a scientifically valid basis for making a causal inference. At the hearing, Defendants argued that Elghobashi's CFD does not provide such a scientifically valid basis. DX19, 10/24/17 Tr. 12:14–13:1, 45:1-9, 70:2-11; 10/26/17 Tr. 78:9-21.

Defendants also cited the *Reference Manual*, which notes that an epidemiological association is necessary for an expert to infer medical causation. Without an association, other evidence is insufficient to support such an inference. *Reference Manual* 221, 598-99. The authors caution that some experts "attempted to use these guidelines to support the

existence of causation in the absence of any epidemiologic studies finding an association. There may be some logic to that effort, but it does not reflect accepted epidemiologic methodology." *Id.* at 599 n.141. Defendants also cited cases concluding that mechanistic plausibility is insufficient to support an inference of causation. *See, e.g.*, *In re Zoloft Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 498–99 (E.D. Pa. 2016) ("Plaintiffs [ ] have cobbled together evidence of biological plausibility, specific causation opinions based on an assumption that general causation has been established, and anecdotal evidence. Taken together, Plaintiffs' potentially admissible evidence supports no more than an association between Zoloft and certain birth defects . . . . Causation must be based upon more than a possibility."), *aff'd*, 858 F.3d 787 (3d Cir. 2017).

In sum, Defendants do not believe the Court ever concluded independently that Elghobashi's CFD is sufficient, by itself, to support general causation. Such a conclusion would be contrary to case law and accepted epidemiological methods. Nor did Defendants ever concede that proposition.

IV. THE NEW INTERNATIONAL CONSENSUS REINFORCES THAT PLAINTIFFS' EXPERTS HAVE MADE AN IMPROPER INFERENCE.

The 2018 ICM is properly before this Court on Defendants' motion for reconsideration. The ICM published the report of its consensus statements online on November 12, 2018, three months after Defendants filed their letter requesting leave to seek reconsideration last August. Dkt. 1428. The Court's order granting leave to file this reconsideration motion did not preclude Defendants from citing the 2018 ICM, and the consensus statements are plainly relevant to the issues here.

Amazingly, Plaintiffs concede the 2018 ICM was correct in concluding, by a vote of 93% to 2%, that "[t]here is no evidence to definitely link FAW [forced air warming] to an increased risk of SSIs/PJIs [surgical site infections/periprosthetic joint infections]." DX2 at 112. Plaintiffs describe this conclusion as "unremarkable." Opp. 40. Plaintiffs also do not dispute that the ICM, in a statement co-authored by Mike Reed, considered Elghobashi's CFD paper, the Observational Study, and the airflow studies, and concluded that they did not collectively represent "strong evidence linking FAW to increased risk of SSI." DX2 at 114; *id.* n.1 (Observational Study), 4 (Legg 2012), 5 (Legg 2013), 6 (Dasari), 7 (Belani), 8 (Elghobashi). And Plaintiffs further concede that "[n]o evidence can provide such a link other than high-level evidence such as a 'randomized prospective trial.'"[5] *Id.* Plaintiffs' concessions are perplexing because their experts *insist* that their opinions are supported by strong evidence, relying on the same studies the 2018 ICM considered. *See, e.g.*, PX1, Jarvis Rpt. 12 ("These studies provide substantial evidence of the patient safety risk posed by the Bair Hugger FAWs.").

Nonetheless, Plaintiffs argue that the 2018 ICM still supports their experts' opinions because the ICM acknowledges (as did the 2013 ICM) the "theoretical risk posed by [forced air warming]." DX2 at 114. But case law is clear that a "theoretical risk" is insufficient to support causation. *See, e.g.*, *Mirena IUD*, 169 F. Supp. 3d at 450; *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1303 (M.D. Fla. 2007) ("This Court's gate-

[5] Of course, Plaintiffs do not and cannot cite any randomized prospective trial that finds that the Bair Hugger system causes or is even associated with an increased risk of infection.

keeping function is to ensure that opinions based on mere theory do not reach the jury . . . [An expert's] opinion may very well be correct. His conclusions may be proven true. But at this point there is a gap between the data and the opinions he proffers."); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003) ("While hypothesis is essential in the scientific community because it leads to advances in science, speculation in the courtroom cannot aid the fact finder in making a determination of whether liability exists."); *Johnson v. Avco Corp.*, 702 F. Supp. 2d 1093, 1108-09 (E.D. Mo. 2010) ("We do not allow witnesses to tell juries that in their expert opinion something happened simply because it is possible.").

Plaintiffs cannot paper over the fundamental fact that their experts disagree with the strong consensus of the ICM and the votes of 93% of the ICM delegates. At best, they are on the side of the 2% (though we do not know the reasons why those 2% disagreed with the consensus statement – they may well have disagreed with the ICM's further statement that "[a]lternative methods of warming can be effective and may be used."). DX2 at 112. As this Court noted in *Wagner v. Hesston Corp.*, No. Civ.03-4244 (JNE/JGL), 2005 WL 1540135, *5 (D. Minn. June 30, 2005), the Court may weigh the fact that a theory is "able to attract only minimal support within the community" against its admissibility. *See id.* (*quoting Daubert v. Merrell Dow Pharms., Inc*, 509 U.S. 579, 594 (1993)).

V. IN THE ALTERNATIVE, THE COURT SHOULD CERTIFY GENERAL CAUSATION UNDER SECTION 1292(B).

If the Court concludes that Plaintiffs' medical experts remain admissible under Eighth Circuit law, Defendants request that the Court certify its Order for immediate interlocutory appeal under 28 U.S.C. § 1292(b).

Contrary to Plaintiffs' contention, the standard in *Glastetter v. Novartis Pharms. Corp*., 252 F.3d 986 (8th Cir. 2001), and the more permissive standard cited in the Court's Order, are not the same. ECF No. 1024 at 3 (*quoting Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 864 (8th Cir. 2004)). As Defendants explained in their Memorandum, the "fundamentally unsupported" language cited by this Court is unique to a strand of Eighth Circuit case law and originates in pre-*Daubert* decisions. It is not followed by any other Court of Appeals and is not followed consistently by the Eighth Circuit (*Glastetter* is the key example). The point is not that *Glastetter* is stricter than *Daubert* – it is not. The point is that the "fundamentally unsupported" language in this strand of Eighth Circuit law finds no basis in *Daubert* or Fed. R. Evid. 702, and significantly curtails the district court's gatekeeping function. This case is well suited to resolving these conflicting strains of Eighth Circuit law and potentially bringing Eighth Circuit law back into line with other Circuits.

Certification would materially advance the termination of this litigation. Plaintiffs' medical experts' opinions are inadmissible under the *Glastetter* standard. If the Eighth Circuit agrees that *Glastetter* properly states the controlling standard, Plaintiffs' experts' opinions must be excluded and summary judgment granted in all cases.

Plaintiffs argue that certification is "pointless" because Defendants have already cross-appealed the Court's general causation Order in *Gareis*. It is not pointless, because the Eighth Circuit has many grounds for affirming the *Gareis* verdict without reaching the admissibility of Plaintiffs' experts' causation opinions. Certifying under Section 1292(b) provides an additional basis for the Eighth Circuit to consider the general causation issue in the near term, to the benefit of the entire MDL.

CONCLUSION

For all these reasons, as well as the reasons stated in Defendants' Memorandum, this Court should reconsider its December 2017 order, exclude Plaintiffs' medical experts and Elghobashi and his CFD pursuant to Fed. R. Evid. 702, and grant summary judgment on general causation in favor of Defendants. In the alternative, the Court should certify the general causation issue to the Eighth Circuit pursuant to Section 1292(b).

Dated: March 14, 2019

Respectfully submitted,

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